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| EXAMINER |
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HYUN, PAUL SANG HWA

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| ART UNIT | PAPER NUMBER |
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1743

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/04/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/661,836

Applicant(s)

MOON ET AL.

Examiner

Paul S. Hyun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 18,33,35,36,39,43,44 and 52-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17,19-32,34,37,38,40-42 and 45-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/7/04, 6/22/04, 6/21/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

REMARKS

Claims 1-57 are currently pending. In response to the written restriction requirement dated 1/04/07, Applicants elected to prosecute claims 1-53 without traverse. Accordingly, claims 54-57 are withdrawn from further consideration by the Examiner as being drawn to a non-elected invention.

Further, in response to the election of species requirement, Applicants elected the prosecution of claims 2, 19-25, 32, 34, 38 and 48 without traverse. Accordingly, claims 18, 33, 35, 36, 39, 43, 44, 52 and 53 are withdrawn from further consideration by the Examiner. However, these claims are subject to rejoinder upon the allowance of the generic claims.

In summary, only claims 1-17, 19-32, 34, 37, 38, 40-42 and 45-51 will be considered on the merits.

Claim Objections

Claims 1, 19, 20, 24 are objected to because of the following informalities:

In claim 1, the word "microbead" should be inserted between the words "each" and "having" in line 3 to clarify that the elongated body and the embedded code are referring to the microbeads, not the positioning device. The word "step" in line 2 should be changed to "steps."

In claim 19, the word "having" should be excised.

In claims 20 and 24, the word "cuvette-like" should be changed to "cuvette-like device".

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Appropriate corrections are required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims **1-17, 19-32, 34, 37, 38, 40-42 and 45-51** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-17, 19-32, 34, 37, 38, 40-42 and 45-51 of copending Application No. 11/063,665. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims **1-10** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 11/226,892. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **3, 8-15, 17, 19-25, 30-32, 34, 37 and 49** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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There is insufficient antecedent basis for the following limitations in the claims:

Claims 3, 9-15, 30, 34 and 49 recite the limitation "the grooves".

Claims 8, 9, 17, 19, 30-32, 34, 37 and 49 recite the limitation "the plate".

Claims 10-12, 14 recite the limitation "the diameter" without first establishing that it has a circular dimension.

Claim 17 recite the limitation "the step of agitating the plate".

Claims 3, 8-15, 17, 19-25, 30-32, 34, 37 and 49 cannot be examined on the merits without speculating the scope of the claims. The lack of antecedent basis for the limitations render the claimed methods indefinite. Therefore, the claims will not be examined on the merits.

Claims 8 and 9 recite the limitation "including..." It is unclear whether the limitations proceeding the "including" are intended to be exemplary or actually limiting.

Claim 20 recites a cuvette-like device comprising an opening. However, claim 19 recites that the cuvette-like device comprises three walls and a cover. It is not clear where the opening of the device is located.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **1, 2, 4, 6, 7, 16, 26-29, 40, 47, 48, 50 and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. (US 6,383,754 B1) in view of Lee (US 4,053,433).

Kaufman et al. disclose a method for aligning fluorescent microbeads as well as a microplate for aligning the microbeads (see col. 48). The method comprises the steps of providing color-encoded microbeads to a microplate, and aligning the microbeads within the wells of the microplate in a predetermined orientation such that the fluorescence of the microbeads can be measured by a camera (see line 55, col. 20). The fluorescence is used to correlate the chemical content complexed with the microbeads. The method disclosed by Kaufman et al. differs from the claimed method in that Kaufman et al. do not disclose that the microbeads are elongated.

Lee discloses fluorescent microparticles for tagging analytes. The microparticles can be cylindrical in shape (see line 62, col. 2) and made from glass (see line 33, col. 3). The diameter of the microparticles can be 50-250 microns (see line 55, col. 2). Lee discloses that the microparticles are easy to decode (see lines 15-20, col. 2). Although the reference does not explicitly disclose the length of the cylindrical microparticles,

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given that the particles are "micro" and cylindrically shaped, it would have been obvious to maintain the length of the particles between 100-500 microns.

In light of the disclosure of Lee, it would have been obvious to use the microparticles disclosed by Lee to conduct the method disclosed by Kaufman et al. since the microparticles disclosed by Lee are easy to decode.

With respect to claim 7, although Kaufman et al. do not explicitly disclose that the microbeads are aligned in relation to their pitch and yaw axis, the reference discloses that the microbeads align by ligating a specific hexamer. It is apparent that the microbeads would align in relation to their pitch and yaw axis when they ligate the hexamer.

With respect to claims 50 and 51, the limitations directed towards the microbeads do not further limit the claimed aligning apparatus because the microbeads are not claimed as being a part of the apparatus.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Lee as applied to claims 1, 2, 4, 6, 7, 26-29, 47, 48, 50 and 51, and further in view of Spencer et al. (US 6,242,056 B1).

Neither Kaufman et al. nor Lee disclose that the microbeads comprise holographic codes.

Spencer et al. disclose microbeads comprising holographic codes as a means to identify the microbeads (see line 38, col. 3). The reference discloses that holographic codes can be used instead of fluorescence. In light of the disclosure of Spencer et al., it

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would have been obvious to one of ordinary skill in the art to provide the modified microbeads disclosed by Kaufman et al. and Lee with holographic codes instead of fluorescent color given that they are obvious variations of ways to identify microbeads.

Claim **38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Lee as applied to claims 1, 2, 4, 6, 7, 26-29, 47, 48, 50 and 51, and further in view of Provonchee (US 4,701,754).

Neither Kaufman et al. nor Lee disclose a disk.

Provonchee discloses a circular microplate (see lines 25-35, col. 2). The reference discloses that the shape of the microplate is essential so that it conforms with the arrangement of the means for scanning the contents of the microplate.

In light of the disclosure of Provonchee, it would have been obvious to one of ordinary skill in the art to conduct the modified method disclosed by Kaufman et al. and Lee using a circular microplate if the circular arrangement conforms better with the detecting means (i.e. camera).

Claim **41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Lee as applied to claims 1, 2, 4, 6, 7, 26-29, 47, 48, 50 and 51, and further in view of Boseé (US 6,881,789 B2) and Woudenberg et al. (US 6,660,147 B1).

Neither Kaufman et al. nor Lee disclose the step of providing a plate comprising radial channels.

Boseé discloses a method for immobilizing analytes to microspheres wherein the method comprises the step of centrifuging the microspheres during the immobilization process to facilitate the immobilization (see Example IV, col. 21). Woudenberg et al. disclose a centrifuge device comprising radial/concentric channels. The radial channels facilitate separation (see lines 1-20, col. 8).

In light of the disclosure of Boseé and Woudenberg et al., it would have been obvious to one of ordinary skill in the art to centrifuge the microparticles in the modified method disclosed by Kaufman et al. and Lee using a centrifuge device with radial channels to isolate the microparticles.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Lee as applied to claims 1, 2, 4, 6, 7, 26-29, 47, 48, 50 and 51, and further in view of Boseé (US 6,881,789 B2) and Bowley (US 4,762,420).

Neither Kaufman et al. nor Lee disclose the step of arranging the microplate on a rotating disk.

Boseé discloses a method for immobilizing analytes to microspheres wherein the method comprises the step of centrifuging the microspheres during the immobilization process (see Example IV, col. 21). Bowley discloses a method for centrifuging the contents of a microplate (see lines 35-40, col. 1).

In light of the disclosure of Boseé and Bowley, it would have been obvious to one of ordinary skill in the art to centrifuge the microparticles in the modified method

disclosed by Kaufman et al. and Lee to facilitate the immobilization of the microparticles to the wells of the microplate.

Claims **45 and 46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaufman et al. in view of Lee as applied to claims 1, 2, 4, 6, 7, 26-29, 47, 48, 50 and 51, and further in view of Ravkin et al. (US 2003/0129654 A1).

Neither Kaufman et al. nor Lee disclose microbeads with protrusions.

Ravkin et al. disclose coded microparticles used for tagging analytes wherein the microparticles comprise identification means in the form of surface relief features. Surface relief generally includes regular or irregular recesses and/or protrusions that extend inward or outward, respectively, along at least one axis or radius relative to adjacent particle surfaces. Exemplary surface relief features may include grooves, ridges, dimples, bumps, through-holes, pockets, projections, ripples, and/or flaps, among others, and may have any suitable shape and size. The surface relief of a particle corresponds to or at least partially determines the particle code (see [0186]).

In light of the disclosure of Ravkin et al. it would have been obvious to provide the microparticles in the modified method disclosed by Kaufman et al. and Lee with through-holes or protrusions to provide another means to identify the microparticles.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
3/29/07


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